JUL 1 8 2003

APPENDIX 6: 510 (K) SUMMARY K03163/

510(k) Summary
As required by 807.92
For ERGO SRS
Prepared on January 17, 2003

Submitted by: 3D Line USA, Inc.
11419 Cronridge Drive, Suite 15
Owings Mills, MD 21117

Tel. 410-581-6701 Fax: 410-581-9007

Contact Person: Nader Salehi
Vice President

Device Trade Name: **Stereotactic Body Frame**

Common Name: Stereotactic patient positioning system

Classification: Medical charged-particle radiation therapy system, Class II
Sec. 21 CFR 892.5050

Predicate Device: **Stereotactic Body Frame,** K960338

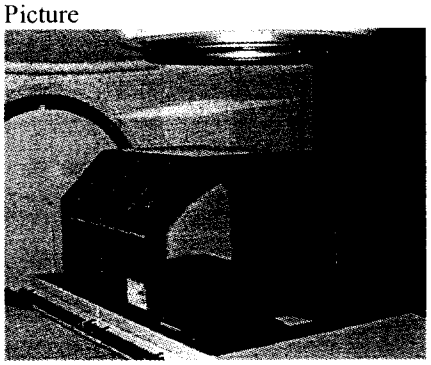
Manufactured by: Elekta Instrument AB, St. Larsgatan 8 S-582, Linkoping, Sweden

Description of the Device: **Stereotactic Body Frame** is a spatial reference system external to the body of a patient undergoing radiotherapy treatment that provides accurate positioning of the patient in spatial registration with diagnostic images and a radiotherapy treatment plan.

Intended Use for the Device: It is intended for use in the planning and conduct of 3 dimensional radiation therapy with a linear accelerator.

Substantial Equivalence to Predicate Device: 3D line's **Stereotactic Body Frame** is substantially equivalent to Elekta Instrument AB's **Stereotactic Body Frame.** A comparison of clinically relevant characteristics is given below.

Statement of Substantial Equivalence to Stereotactic Body Frame of Electa Instrument AB (K960338)

Characteristics	Body Frame	Elekta Body Frame
Indication **(Intended Use & Device Description)**	The intended use of the body frame is patient fixation, localization and centering for radiotherapy treatments of tumoral lesions **in the body**. These functions are obtained by means of a fixation plate (the base plate) that is both connected to the patient (with thermoconformable mask or cushion) and to the LINAC couch.	Same intended use.
Characteristics	**Material:** Carbon-fiber and plexiglass Picture 	**Material:** Plastic and aluminum Picture 
Compatibility with software	Compatible with ERGO-SCT	Compatible with commercially available software planning.
Similarities in Design	➢ Usage of reference system that is external to the patient's body ➢ Usage of stereotactic coordinates to reproduce the coordinates of a target in both diagnostic and treatment procedures ➢ Copper indicators for determination of targte coordinates on CT ➢ Can be used for stereotactic radiosurgery (SRS) or stereotactic radiotherapy (SRT).	
Differences in Design	➢ To be used with CT only ➢ No arc ruler used, but a frame with coordinates scales ➢ Localization is achieved without putting references on the patient's skin.	➢ Can be used with CT and MRI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

Mr. Nader Salehi
Vice President
3D Line USA, Inc.
11419 Cronridge Drive Suite 15
OWINGS MILLS MD 21117

Re: K031631
Trade/Device Name: Stereotactic Body Frame Cod. 70-1A
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: April 14, 2003
Received: May 27, 2003

Dear Mr. Salehi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Applicant: _3D Line USA, Inc._____

510(k) Number (if known): K031631

Device Name: __**Stereotactic Body Frame Cod. 70-1A** _____

Indications For Use:

Stereotactic Body Frame Cod. 70-1A is patient localization system for use in stereotactic radiosurgery. It is an accessory to linear accelerators used for radiation therapy. It is indicated for use in the planning and conduct of 3 dimensional radiation therapy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031631

Prescription Use ✓
(Per 21 CFR 801.109)